REMARKS/ARGUMENTS

1. Claims 1-20 are pending in this application. Claims 21-26 have been withdrawn from consideration. No new matter has been added.

Regarding the Claim Rejections under 35 U.S.C. 102(b)

2. Applicant acknowledges the quotation of the appropriate paragraph of 35 U.S.C. 102 that forms the basis for the rejections under this section made in the office action.

3. Claims 1, 4-8, 11, 12, 16 - 20 were rejected under 35 U.S.C. 102(b) as being anticipated by Reddy (U.S. Pat. No. 5,168,881). Applicant respectfully disagrees with this anticipation rejection in light of the arguments presented below.

Regarding currently amended Claims 1 and 16, and previously presented Claims 17 and 18, Reddy discloses a *thin*-walled condom, which is intended to be flexible (Reddy Col. 2, lines 36, 37) (emphasis added). Reddy's thin-walled condom is not meant to retain its shape, but rather is unrolled and extended into a body cavity by penetration of an erect penis. (Reddy Col. 3, lines 10 – 45). The Applicant's invention, on the other hand, is a *thick*-walled condom, which is intended to be semi-rigid and retain its shape before, during, and after use. Reddy's thin-walled condom is flexible enough to be unrolled by an erect penis, while Applicant's thick-walled condom retains its shape and can be inserted into a sexual orifice without the need for an erect penis.

Additionally, the Reddy condom requires an erect penis (or some other device) to unroll the condom. Even though the Reddy condom does not have to be rolled out over the male sex organ to be fastened to the user, an erect penis (or some other device) is required to telescope the condom into the passive partner's sexual orifice (Reddy Col. 3, 21 – 27). Until an erect penis (or some other device) telescopes the condom, it remains outside of the passive sexual partner's orifice (Reddy

Col. 3, 8 – 32). Because Applicant's condom is thick-walled and semi-rigid, it can be placed into the orifice of a passive sexual partner without the need of an erect penis (or some other device). There is no telescoping or extension into the sexual orifice of the passive sexual partner with the Applicant's condom.

While both Reddy and Applicant's condom may be considered "universal" and "unisex", there are significant differences in the functionality of each condom. Reddy's condom requires modification to the device depending on whether the device is secured to an active male partner, or a passive sexual partner. Applicant's condom, however, requires no modification when used by either an active or passive partner; the exact same condom can be used multiple times between multiple partners for multiple sexual uses without modification.

Further, Reddy does not disclose the use of biocompatible materials. Reddy discloses the use of materials "such as natural rubber or synthetic rubber (e.g., silicone rubber)" and other plastics (Reddy Col. 9, 22 – 25). Reddy does not disclose USP class six thermoplastic elastomers. Reddy never discloses the use of biocompatible materials. Applicant uses "biocompatible material" to classify a subset of materials that have been approved by the FDA, which is not mentioned in Reddy.

Regarding currently amended Claim 4, Reddy discloses a collar that has straps, where these straps keep the collar at the surface of the entrance to the vagina or anus (Reddy Fig. 5, Object 36). Applicant's amended Claim 4, however, discloses a collar that keeps the condom in place without the use of rings, straps, or other metal or hard plastic devices.

Regarding currently amended Claim 5, Reddy discloses a thick-walled shield, not a thick-walled condom (Reddy Col. 9, 17 – 30). The walls of the tubular sheath of the Reddy condom are thin, and are not used to facilitate insertion into the orifice. Applicant's condom, on the other hand, has a tubular sheath with thick walls, and these semi-rigid walls facilitate the insertion into the sexual orifice of the passive user.

Regarding previously presented Claim 6, Reddy discloses a means of protection (Reddy Fig. 5, 35) and a means of securing the device (Reddy Fig. 5, 36). The means of protection is the thick-walled shield, designed to prevent transmission of disease (Reddy Col. 8, 35 – 40). The straps (Reddy Fig. 5, 36) are attached to the shield (Reddy Fig. 5, 35) and these straps are used to secure the device, not the shield. Applicant's condom has two different means of securing it to a user. The first mean is to secure it to the active male wearer. The second is a separate and distinct means of securing it within the orifice of the passive wearer during intercourse.

Regarding previously presented Claim 7, Reddy discloses a shield that prevents the transmission of disease from one person to another (Reddy Col. 8, 35 – 40). Applicant's condom, however, not only helps to prevent the transmission of disease from one person to another, it also is a means for retaining and securing within the orifice of a passive wearer during intercourse. This dual purpose is not disclosed nor anticipated by Reddy. Again, a key component to the application under consideration is the fact that Resnic's condom is rigid enough to be inserted without first unrolling it over an erect penis; therefore since it will not be withdrawn from the orifice with the penis, there must be means of ensuring that it does not become lodged in the orifice. Rensic's shield provides just this function.

Regarding currently amended Claim 8, Reddy discloses a shield that completely surrounds the scrotum to prevent the exchange of bodily fluids (Reddy Col. 4, 40 – 48, and Reddy Cols. 8 – 9). This shield that surrounds the scrotum is not used to secure the device to the active male wearer.

Applicant's condom, on the other hand, is merely a strap that encircles the scrotum, which is used solely for securing the device to the active male wearer. Additionally, Reddy does not disclose using materials from the group consisting of biocompatible polymers; it is Applicant that is making this disclosure.

Regarding currently amended Claim 11, Reddy discloses a shield, discussed above, that completely surrounds the scrotum and is designed to prevent the exchange of bodily fluids (Reddy Col. 4, 40 – 48, and Reddy Cols. 8 – 9). Reddy does not disclose straps that enclose the scrotum of the active male wearer, nor does Reddy disclose a strap that is stretched around the testicles that inhibits blood flow away from the penis. Applicant discloses a strap that encircles the testicles, which, in turn, both secures the device to the active male wearer as well as constricts the flow of blood away from the penis and causes an erection to be substantially maintained for an extended period of time.

Regarding previously presented Claim 12, Reddy discloses a condom that requires an erect penis, or some other device, to extend the condom into the passive sexual partner (Reddy Col. 8 – 32). The Reddy condom can be positioned outside of the orifice without requiring insertion of an erect penis, hand, tool, or the like, but remains outside the orifice until an erect penis, hand, tool, or the like, telescopes the condom into the orifice. Reddy does not disclose a condom with a tubular sheath that has semi rigid walls, nor does Reddy disclose a condom that is shape retaining. Applicant's condom does have semi-rigid walls, and does retain its shape. It does not require an erect penis to attach it to the active male wearer, nor does is require an erect penis, hand, tool, or the like to insert it into the sexual orifice of a passive sexual partner.

Regarding previously presented Claims 19 and 20, Reddy does not disclose a piloting assembly that is made out of biocompatible materials, nor does Reddy disclose at any time the specific use of biocompatible materials anywhere in the Reddy patent. Additionally, Reddy discloses using a dipping process to create the device. However, biocompatible materials cannot be used in a dipping process to create the device because the silicone would degrade off of the mold, and the tensile strength would not be strong enough to withstand breakage. Therefore, Reddy did not disclose, nor even anticipate using biocompatible materials to create the desired device.

Therefore, as Applicant believes that currently amended Claims 1, 4, 5, 8, 11, and 16, and previously presented Claims 6, 7, 12, and 17 - 20, disclose novel features or elements that are not disclosed in Reddy, Applicant believes that claims 1, 4 – 8, 11, 12, and 16 - 20 are not anticipated by Reddy and are now in condition for allowance.

Regarding the Claim Rejections under 35 U.S.C. 103(a)

4. Applicant acknowledges the quotation of the appropriate paragraph of 35 U.S.C. 103 that forms the basis for the rejections under this section made in the office action.

5. Claims 3, 9, and 13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reddy (U.S. Pat. No. 5,168,881) in view of Schwartz (U.S. Pat. No. 5,513,652). Applicant respectfully disagrees with the obviousness rejection of Claims 3, 9, and 13 in light of the arguments presented below.

Regarding currently amended Claims 3 and 13, and previously presented Claim 9, Reddy does disclose a collar that extends outwardly as a contiguous shield, and Schwartz does disclose a condom with a tapered, narrowed neck (Schwartz Fig. 4, 22). However, the design of the neck, and the purpose of that design is significantly different. The tapered neck in the Schwartz condom was designed to be less than the diameter of the erect penis so as to maintain an erection by impairing the flow of blood away from the penis. The Applicant's condom, on the other hand, has a design where the diameter of the neck is not necessarily less than the diameter of an erect penis. The contour of the neck is designed to be more readily retained with muscle contraction by the passive user within a sexual orifice. The purpose of the tapered neck is different in the Schwartz and Applicant's condom, and each is designed with that different purpose in mind. Neither Reddy nor Schwartz disclose, teach, or suggest a design to be more readily retained with muscle contract by the passive user within a sexual orifice.

Therefore, because Applicant believes that currently amended Claims 3 and 13, and previously presented Claim 9, contain features or elements that are not disclosed, taught, or suggested in either Reddy or Schwartz, and that are not solely for design purposes, but rather provide useful functionality in regards to the use of the apparatus, Applicant believes that claims 3, 9, and 13 are not obvious in light of any of the cited references and is now in condition for allowance.

6. Claims 10, 14, and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reddy (U.S. Pat. No. 5,168,881) in view of Alla (U.S. Pat. No. 5,992,415). Applicant respectfully disagrees with the obviousness rejection of Claims 10, 14, and 15 in light of the arguments presented below.

Regarding previously presented Claims 10 and 14, and currently amended Claim 15, Applicant does claim a reservoir that is located at the closed end of the condom which is capable of retaining fluid, but Applicant does not claim a reservoir that eases the installation and retention of the condom. Nor is Applicant's reservoir made of foam, but rather Applicant claims in claim 15 a reservoir that comprises a foam, or otherwise sponge-like absorbent, that is used to absorb bodily fluids.

While Reddy does not teach of a reservoir, Alla does teach a reservoir that is located at the closed end of the condom (Alla Fig. 2, 28). However, the design of the reservoir in Applicant's patent is significantly different and advantageous to that taught in Alla. Applicant's unique design includes a flange that has a hole in the middle, which funnels down toward the closed end of the condom. This flange works similar to that of a one-way valve, allowing bodily fluids to enter the reservoir, but prevents its escape and subsequent backflow.

Therefore, because Applicant believes that previously presented claims 10 and 14, and currently amended claim 15, contain features or elements that are not disclosed, taught, or suggested in either Reddy or Alla, and that are not solely for design purposes, but rather provide useful functionality in regards to the use of the apparatus, Applicant believes that claims 10, 14, and 15 are not obvious in light of any of the cited references and is now in condition for allowance.

7. Generally, all of Applicant's claims are not disclosed, taught, or otherwise suggested in Reddy, Alla, or Schwartz.

Applicant has built upon the prior art to create a condom that has superior features and functionality over the prior art. Even by combining Reddy, Alla, and Scwartz, a person of ordinary skill in the art would not create Applicant's superior condom. Having a semi-rigid thick-walled condom has not been taught, disclosed, or otherwise suggested in any of the prior art. The unique design of the condom allows for use with or without an erect penis, and can be secured and retained by either the active male wearer or the passive sexual partner. Prior art would not allow for a flaccid penis to be inserted into a condom, and then in turn be able to insert the condom into a sexual orifice.

Additionally, Applicant has filled a need where others have failed. The prior art has strived to create a universal, unisex condom that will protect each user of the condom. None of these condoms, however, could be inserted without the use of an erect penis or other device. Prior art has straps as a means of securing the condom to the active male partner, but these straps are bulky and condom where the exact same condom can be secured to the active male partner, or the passive sexual partner without any modification to the device. Application has also chosen a specific group of materials for the wall of the condom, and the prior art has never suggested using these specific biocompatible materials to create the wall of the condom.

Finally, condoms, in some form or another, have been around for thousands of years, and were publicly demonstrated as early as the 15th century. In terms of commercial success, it would make sense that an "obvious improvement" over existing patents and applications would result in modest funding at best for its creator. However, in this case, Applicant has received substantial government funding to test and manufacture this device. Indeed, Mr. Resnic has obtained a grant for his condom from the NIH, which is an extremely prestigious acknowledgment of the uniqueness of his condom.

Research for Resnic's condom was reviewed by the Center for Scientific Review at the National Institutes of Health (a copy of this review is attached as Exhibit 1). Resnic was awarded and received one of the highest awards (more than double) for a Phase I Research Study.

In their opinion, as stated in their Summary Statement, 08/08/05, "This product would provide an alternative that would be stronger than latex condoms yet provide better sensation. It is highly significant in proposing to develop a condom that will potentially have a higher acceptance rate than the latex condom. This product would provide an alternative that would be stronger than latex condoms yet provide better sensation.

If successfully marketed, this new condom may improve condom acceptability among non-condom users. This product, if proven acceptable for human use **could revolutionize the male condom** with respect to enjoyment while providing protection from disease and pregnancy. It is clear that alternative products are needed to promote condom use, and the ...... condom has the potential to enhance acceptance and use among those that engage in risky behaviors. Mr. Resnic's imagination and desire to provide more acceptable and user-friendly products for consumers is admirable."

Mr. Resnic began a Phase 1 Study for clinical trials of the new condom on June 25, 2006, fully funded by the National Institutes of Health. This study will be followed by a larger Phase 2 Study to submit to the FDA for pre-market approval in 2008.

The CSR committees at NIH included;

meeting roster

Center for Scientific Review Special Emphasis Panel

CENTER FOR SCIENTIFIC REVIEW

ZRG1 EMNR-E (10) B

October 28, 2004 - October 29, 2004

CHAIRPERSON

GORODESKI, GEORGE I, MD, PHD

PROFESSOR

DEPARTMENT OF REPRODUCTIVE BIOLOGY

CASE WESTERN RESERVE UNIVERSITY

DEPARTMENT OF OBSTETRICS & GYNECOLOGY

UNIVERSITY HOSPITALS OF CLEVELAND

CLEVELAND, OH 44106

GREEN, ALLAN , PHD

DIRECTOR

BASSET RESEARCH INSTITUTE

ONE ATWELL ROAD

COOPERSTOWN, NY 13326

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

UNIVERSITY OF TEXAS

CIARALDI, THEODORE P., PHD

SOUTH WESTERN MEDICAL CENTER

PROJECT ENDOCRINOLOGIST DALLAS, TX 75390

DEPARTMENT OF MEDICINE

UNIVERSITY OF CALIFORNIA AT SAN DIEGO HUNNICUTT,

GARY R, PHD

LA JOLLA, CA 92161

NEUMAN, MICHAEL R., MD, PHD

FRANKLIN, FRANK A JR, MD, PHD PROFESSOR

PROFESSOR OF PEDIATRICS DEPARTMENT OF BIOMEDICAL ENGINEERING

UNIVERSITY OF ALABAMNA AT BIRMINGHAM MICHIGAN TECHNOLOGICAL UNIVERSITY

CHILDREN'S HOSPITAL HOUGHTON, MI 499311295

BIRMINGHAM, AL 35233

ROACH, PARIS , MD

GABELNICK, HENRY L, PHD ASSOCIATE PROFFESSOR

DIRECTOR INDIANA UNIVERSITY

CONRAD PROGRAM/OB-GYN DEPT OF MEDICINE/ DIVISION OF ENDOCRINOLOGY

EASTERN VIRGINIA MEDICAL SCHOOL INDIANAPOLIS, IN 462025111

ARLINGTON, VA 22209

ROSEN, EVAN D, MD, PHD

ASSISTANT PROFESSOR OF MEDICINE

BETH ISRAEL DEACONESS MEDICAL CENTER

BOSTON, MA 02215

SAIRAM, RAM M, PHD

DIRECTOR

MOLECULAR REPRODUCTION RESEARCH LABORATORY

CLINICAL RESEARCH INSTITUTE OF MONTREAL

MONTREAL, QUEBEC, H2W 1R7

CANADA

SMITH, CAROLYN L, PHD

ASSOCIATE PROFESSOR

DEPARTMENT OF MOLECULAR & CELLULAR BIOLOGY

BAYLOR COLLEGE OF MEDICINE

HOUSTON, TX 77030

WALKER, WILLIAM F, PHD

ASSOCIATE PROFESSOR

DEPARTMENT OF BIOMEDICAL ENGINEERING

UNIVERSITY OF VIRGINIA

CHARLOTTSVILLE, VA 22903

WEISS, GERSON , MD

PROFESSOR AND CHAIR

DEPARTMENT OF OBSTETRICS & GYNECOLOGY

NEW JERSEY MEDICAL SCHOOL

UNIV OF MEDICINE & DENTISTRY OF NJ

NEWARK, NJ 07103

GUPTA, SANJEEV , MD, PHD

PROFESSOR OF MEDICINE AND PATHOLOGY

ALBERT EISTEIN COLLEGE OF MEDICNE

BRONX, NY 10461

SCIENTIFIC REVIEW ADMINISTRATOR

KRISHNAN, KRISH , PHD

CENTER FOR SCIENTIFIC REVIEW

NATIONAL INSTITUTES OF HEALTH

BETHESDA, MD 20892

COLFAX, GRANT N, MD

DIRECTOR OF HIV PREVENTION STUDIES

SAN FRANCISCO DEPT OF PUB HEALTH

AIDS OFFICE-HIV RESEARCH SECTION

SAN FRANCISCO, CA 94102

COON, DAVID W, PHD

RESEARCH SCIENTIST

DEPT. OF SOC. & BEH. SCIENCES

ARIZONA STATE UNIVERSITY

GLENDALE, AZ 853064908

DI NOIA, JENNIFER , PHD

ASSOCIATE RESEARCH SCHOLAR

SCHOOL OF SOCIAL WORK

COLUMBIA UNIVERSITY

NEW YORK, NY 10025

JOHNSON, MALLORY O, PHD

RESEARCH SPECIALIST

CENTER FOR PREVENTION STUDIES

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

SAN FRANCISCO, CA 94105

METSCH, LISA R, PHD

ASSOCIATE PROFESSOR

DEPARTMENT OF EPIDEMIOLOGY AND PUBLIC HEALTH

SCHOOL OF MEDICINE

UNIVERSITY OF MIAMI

MIAMI, FL 33136

OBERMAYER, JAMI L, PHD

RESEARCH SCIENTIST

PICS, INC

RESTON, VA 20191

SAFREN, STEVEN A, PHD
ASSISTANT PROFESSOR, HARVARD MEDICAL SCHOOL
DEPARTMENT OF PSYCHIATRY
MASSACHUSETTS GENERAL HOSPITAL
BOSTON, MA 02115

CARTER, ELI , BS
DIRECTOR
FAMILY HEALTH INTERNATIONAL
RESEARCH TRIANGLE PARK, NC 27709

SCIENTIFIC REVIEW ADMINISTRATOR
RUBERT, MARK P., PHD
SCIENTIFIC REVIEW ADMINISTRATOR
CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892

CONCLUSION

Applicant has addressed all of the objections and rejections raised by the Examiner. Attorney for Applicant certifies that the claims as amended introduce no new matter to the application.

Attorney for Applicant has carefully reviewed the cited references, namely the Reddy, Schwartz, and Alla patents, and believes that the new claims presently on file in the subject application are patentably distinguishable with respect to the prior art. In view of the amendments to the disclosure and the remarks submitted herein, Applicant submits that all of the new claims of record are in condition for allowance and respectfully requests that a Notice of Allowance be issued in this case in due course.

If it is felt for any reason that direct communication with Applicant's attorney would serve to advance prosecution of this application to allowance, the Examiner is invited to contact the undersigned, attorney of record in this case, Eric Hanscom, Esq., at one of the listed below numbers or at his below listed e-mail address.

Dated: July 31, 2006

Respectfully Submitted,

LAW OFFICES OF ERIC HANSCOM

By ______________________________

Eric Hanscom

Eric Hanscom

Law Offices of Eric Hanscom

7395 Portage Way

Carlsbad, CA 92011

Telephone: (760) 804-1712

Facsimile: (760) 494-3014

Email: Eric@Hanscom.com

In their opinion, as stated in their Summary Statement, 08/08/05, "

CONCLUSION

Applicant has addressed all of the objections and rejections raised by the Examiner. Attorney for Applicant certifies that the claims as amended introduce no new matter to the application. Attorney for Applicant has carefully reviewed the cited references, namely the Reddy, Schwartz, and Alla patents, and believes that the new claims presently on file in the subject application are patentably distinguishable with respect to the prior art. In view of the amendments to the disclosure and the remarks submitted herein, Applicant submits that all of the new claims of record are in condition for allowance and respectfully requests that a Notice of Allowance be issued in this case in due course.

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Dated: July 31, 2006

Respectfully Submitted,

LAW OFFICES OF ERIC HANSCOM

By ____________________

Eric Hanscom

Eric Hanscom

Law Offices of Eric Hanscom

7395 Portage Way

Carlsbad, CA 92011

Telephone: (760) 804-1712

Facsimile: (760) 494-3014

Email: Eric@Hanscom.com

Exhibit 1

8/8/05

STEVEN KAUFMAN M.D.
(301) 435-6989
kaufmans@mail.nih.gov

SUMMARY STATEMENT

(Privileged Communication)
Application Number: 1 R43 HD050805-01A1
Formerly: 1R43AI065089-01
RESNIC, DANIEL
STRATA VARIOUS PRODUCT DESIGN
311 NORTH ROBERTSON BLVD #318
BEVERLY HILLS, CA 90211
Review Group: ZRG1 AARR-G (15)
Center for Scientific Review Special Emphasis Panel
AIDS - EXP. REV.
Meeting Date: 07/13/2005
Council: OCT 2005 *PCC:* CRH -SK
Requested Start: 01/01/2006
Project Title: New Silicone Condom: Feasibility Study
SRG Action: Priority Score: 185
Human Subjects: 30-Human subjects involved - Certified, no SRG concerns
Animal Subjects: 30-Vertebrate animals involved - no SRG concerns noted
Gender:
Minority:
Children:
1A-Both genders, scientifically acceptable
1A-Minorities and non-minorities, scientifically acceptable
1A-Both Children and Adults, scientifically acceptable
Clinical Research - not NIH-defined Phase III Trial
Project Year; 1

TOTAL
Direct Costs
Requested
$180,954

180,954
Estimated
Total Cost
$180,954

$180,954
ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

NEW INVESTIGATOR
ZRG1 AARR-G (15) 2 1 R43 HD050805-01A1
RESNIC, D
1R43HD050805-01A1 RESNIC, DANIEL

RESUME AND SUMMARY OF DISCUSSION: This revised Phase I SBIR application proposes to refine and test a condom made from silicone. They first will fabricate three prototypes to evaluate their structural properties and biocompatibility. Next they will test the condom's acceptability and performance with 10 heterosexual couples and finally they will compare it to standard latex condoms in 36 couples. This is an innovative application that may provide a needed alternative to latex condoms.

The applicant was very responsive to the prior reviews and the present application is much improved. One significant change was the plan now tests the condom as male device only, rather than a unisex device. The committee's high enthusiasm for this application was only slightly diminished by a lack of detailed information about the clinical trials.

DESCRIPTION (provided by applicant): The primary objective of this grant is to refine and test a prototype of the Comfort Condom™: a new condom made from silicone, a material that may offer better sensation and be less prone to breakage than latex or plastic. The Comfort Condom will feature several technological innovations, including: 1) strong, heavy- gauge material that feels like human tissue, creating sensation instead of acting as a filter to it, 2) a loose fit for greater comfort, 3) a discrete scrotal retention band to reduce the likelihood of slippage, and 4) highly stretchable material for better fit and comfort. There are five specific aims: 1. Fabricate three prototypes of the Comfort Condom™ from silicone using liquid injection molding. 2. Confirm that the Class VI medical grade silicone used in the Comfort Condom™ remains biocompatible after the manufacturing process. The completed condoms will undergo laboratory testing for cytotoxicity, sensitization, irritation, and systemic toxicity. All three prototypes will be tested. 3. Assess the structural integrity of the Comfort Condom™ by measuring tensile properties, leakage, permeability, airburst volume, and airburst pressure. All three prototypes will be tested. 4. Compare the safety, acceptability, and performance of the three Comfort Condom™ prototypes. A "Feasibility and Design" study will be conducted with ten heterosexual couples. Each couple will use six condoms (two of each prototype), rate various subjective features of each condom, and report on any breakage, slippage, or adverse events they may experience. 5. Compare the safety, acceptability, and performance of the best Comfort Condom™ prototype with a commercial male latex condom. A "Performance and Acceptability" study will be conducted with thirty-six couples. Each couple will use three Comfort Condoms™ and three latex condoms, rate various subjective features of each condom, and report on any breakage, slippage, or adverse events they may experience. For sexually active couples, condoms used correctly and consistently are the most effective method available to reduce the risk of transmitting HIV and other sexually transmitted infections (STI). Unfortunately, many individuals find latex condoms unacceptable. The development of new and improved condoms is a key component in combating the HIV/AIDS crisis.

CRITIQUE 1:

Significance: This is a phase I application to refine and test a prototype of a silicone condom. **It is highly significant in proposing to develop a condom that will potentially have a higher acceptance rate than the latex condom.** Two primary benefits are advanced for silicone rather than latex: that it may provide better sensation and that it will be less prone to breakage. There would be a high level of significance to developing a condom with these characteristics if it led to increased condom use.

Approach: The steps proposed for testing this condom prototype are appropriate, beginning with pre-clinical test of biocompatibility and structural integrity, followed by assessment of feasibility and design, and evaluation of performance and acceptability. 0The applicant has been responsive to reviewer comments on the initial proposal. The most significant change is that the applicant now proposes to test the new condom as a male device only and not a unisex device. The original proposal sought to demonstrate the feasibility of two innovations: the silicone material and the unisex design. This step is quite responsive and represents an improvement in the application because serious concerns had been expressed with respect to the feasibility of the product for female use. This modification will further address the reviewer concern that the proposal was ambitious with respect of time and budget. However, concerns about completing the work within the allotted time and budget still exist, especially if it is necessary to revise the condom prototypes or address other problems. The applicant has added further biocompatibility tests at the request of the FDA. In addition, the investigator has added information concerning potential problems, including criteria that will be used to establish whether the new condom meets standards of acceptability in each of the two clinical trials.

A key claim of the applicant is that silicone will be less prone to breakage and stronger than latex condoms. If this is not the case, the new condom will not be as desirable as a latex condom, even if more acceptable with respect to sensation. Previous concerns were expressed that the new condom would be likely to break. These concerns would be more fully addressed if the investigator provided information on comparisons of latex to silicone in other relevant health applications and/or compared the silicone condom to a latex condom in the pre-clinical structural testing in order to establish comparability of the two products.

Previous reviewers cited lack of detail with respect to the clinical trials. The applicant has addressed this by providing more information. However, some concerns may be cited with respect to the methods to be followed. Although samples of the questionnaires to be administered are not provided, it appears that there needs to be more data to be collected from couples, as levels of mood, desire, and arousal may play significant roles in reactions to the condoms.

The procedure in the Performance and Acceptability Study (in which three condoms of each type are tested before crossing over to the other type) would seem to maximize the possibility that circumstances unrelated to type of condom would influence the sexual experience (e.g. couple is getting along well during one period of time, less so during another period of time), which might potentially affect condom acceptance.

It is not always clear whether information will be provided separately for each partner, for example on the Condom Use Report. It would seem preferable if this were the case. In addition, at the exit interview it appears that participants will be interviewed together. It might be preferable if interviews were conducted individually with partners, as one partner may tend to accede to the views of the other or may be inhibited with respect to expressing his or her own views with the partner present. This procedure will also permit greater confidentiality for each participant.

It is indicated in section 6.0 that statistical tests will be performed. However, there is no information provided on what these tests will be, or how it will be determined from the data collected whether breakage, slippage, failure rates and acceptability ratings differ among the three condom prototypes in the feasibility and design testing study and between silicone and latex condoms in the performance and acceptability study.

In section 7.0 various standards of acceptability for the condoms to be tested are provided. However, there is no justification provided for the decision to use these specific standards. For example, why is a rate of female genital discomfort less than 20% of the time is acceptable compared to a rate male genital discomfort less than 10% of the time?

Innovation: The proposal is highly innovative with respect to the material for condoms as well as design.

Investigators: The applicant is trained in product design and has significant experience in this area. He has brought together an extremely well qualified team.

Environment: The research environment and facilities to be used in the proposed tests appear appropriate, including Nelson Laboratories and the California Family Health Council. ZRG1 AARR-G (15) 4
1 R43 HD050805-01A1 RESNIC, D

Overall Evaluation: This is a potentially highly significant application. The applicant has been responsive to reviewer comments in modifying the design of the study such that the feasibility of the new condom will no longer be tested for unisex use. There is still some concern with respect to structural properties of the silicone condom. With further specification of procedures for clinical trials, questions arise concerning factors that may affect condom acceptability ratings, the potential need for separate data collection for individual partners, statistical testing of results, and justification for standards of acceptability.

Protection of Human Subjects from Research Risks: 4 Required Points: Additional risks to subjects include embarrassment in providing reactions to condoms and condom use. Male participants may experience embarrassment in recording or reporting penis size. Privacy and confidentiality risks include not only accidental disclosure of information by the researcher but also disclosure of information by the partner. The procedures listed under protection against risk only ensure confidentiality from researcher disclosure.

Gender, Minorities, and Children: Both women and men will be included. Minorities will be included. Children between the ages of 18 and 21 will be included. Data Safety & Monitoring Plan: A data safety and monitoring plan is included but could be addressed more fully.

CRITIQUE 2:

Significance: As stated by the author, condoms used correctly and consistently are the most effective method available to reduce the risk of transmitting STI's including HIV. However, many find latex condoms unappealing and unacceptable for multiple reasons including lack of sensation and latex allergies. **This product would provide an alternative that would be stronger than latex condoms yet provide better sensation.** The overall goal of this project is to refine and test a prototype of the Comfort Condom, a new condom made from silicone.

Approach: The PI has addressed the issues raised by previous reviewers including modification of the goals for Phase I, the currently proposed goals (test as male condom only, allow 8 months) are more reasonable. The PI also provided further detail about the product including information about the greater thickness of the Comfort Condom compared to current latex condoms.

The current application states clear goals for both the first and second trail and has an alternative plan if the criteria are not met from the first trial.

The first trial (4 week study period) will recruit 10 couples to evaluate 2 condoms of each of the 3 prototypes for acceptability, safety, and performance. The criteria (breaks, slippage, genital discomfort, etc) for the feasibility of the first trial are clear and allow for use of none of all three of the prototypes to proceed to the second trial.

The second trial will recruit 36 couples to compare the performance, acceptability, and safety of 3 condoms of the selected prototypes to 3 latex condoms.

Innovation: The author states that the Comfort Condom will feature several technological innovations including 1) stronger, heavier material that feels like human tissue, creating sensation instead of filtering it, 2) a looser fit for greater comfort, 3) a discrete scrotal retention band to reduce slippage, and 4) a highly stretchable material for better fit and comfort. Additionally, the Comfort Condom will be unlike current condoms on the market in three innovative ways a) reusable, therefore increasing use among those without ready access, b) used by males and females (will be further explored), and c) pop up rather than roll down, leading to shorter time to use and thus less interruption during the sex act.

Investigators: PI is the inventor and is well qualified to direct the design and evaluation of this product.

Environment: Acceptable

Overall Evaluation: This current application has addressed the issues raised by previous reviewers. **The product addresses an important issue, has clear goals for Phase I, and has strong potential for commercialization.**

Protection of Human Subjects from Research Risks: Acceptable
Inclusion of Women – 50%, Acceptable
Inclusion of Children – Excluded, Acceptable

CRITIQUE 3:

Significance: The objective of this study is to refine a prototype male silicone condom for clinical comparison with a commercially distributed male latex condom. Requisite pre-clinical testing is planned to determine physical strength parameters and chemical biocompatibility. **If successfully marketed, this new condom may improve condom acceptability among non-condom users.**

Approach: Considering that silicone is used in similar medical devices, it appears appropriate to consider this material for condoms. **The rationale is based on the product's mechanical properties and the perceived acceptability and health benefits.**

Innovation: **This product, if proven acceptable for human use could revolutionize the male condom** with respect to enjoyment while providing protection from disease and pregnancy. It is clear that alternative products are needed to promote condom use, and **the Strata condom has the potential to enhance acceptance and use** among those that engage in risky behaviors.

Investigators: The assembled team of investigators appears more than adequately qualified for this research. **Mr. Resnic's imagination and desire to provide more acceptable and user-friendly products for consumers is admirable.** Dr. Frezieres has a proven track record in condom clinical research and is most qualified to undertake this work.

Environment: The proposed collaboration between the listed organizations is appropriate for this research.

Response to Previous Review: The proposal discusses the plan for physical testing or characterization of the product. Although the test methods specified in the ASTM standards are appropriate for evaluating the prototypes, the methods may need modification to accommodate the 'Strata' design. There is no discussion of testing for the Scrotal Retention Strap. If the purpose of the strap is to prevent slippage, a strength/ breakage requirement must be prescribed. Also, a measurement or test to evaluate the function of the reservoir should be included. Section 3.0 – Pre-Clinical Testing must be expanded to fully describe the proposed testing. Deviations and/or modifications from standard test methods should be discussed.

Protection of Human Subjects from Research Risks: Acceptable
Inclusion of Women Plan: Acceptable
Inclusion of Minorities Plan: Acceptable
Inclusion of Children Plan: Acceptable
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RESNIC, D

Overall Evaluation: This proposal is appropriate for selecting a suitable design for clinical study. However, the pre-clinical testing plan needs further refinement in that the proposal specifies 225 samples for physical testing; 20 for bacteriophage, and 108 for clinical use; total 373. However the budget suggests a total of 250 prototypes. Also, it is recommended that additional specimens be added for possible re-tests, particularly if modified tests are employed.

CRITIQUE 4:

Significance: The significance of the project is very high: more alternatives are needed to latex condoms, both because of allergy and acceptability issues. Silicone-based condoms may provide a reasonable alternative to latex condoms, providing additional comfort and sensitivity.

Approach: The investigator has clearly thought through many research and design issues. The study proposes to 1) fabricate 3 prototypes of a silicone-based condom; 2) perform pre-clinical testing, and 3) test products in phase 1 trials using heterosexual monogamous couples. This seems ambitious in the 9-months period of the grant (especially concerning given the clinical nature of the studies and the potential for long IRB turnaround times); no timeline for each specific task is provided. The Background and Significance section is extremely brief and provides few references to back up many of the statements. In Section D, no information is provided on how various staff on this ambitious project will coordinate and exchange data with one another; this is especially concerning for the pre-clinical aspects of the study, which will be performed by a subcontractor.

Further information should be provided with regard to the clinical aspects of the trial: who will assess the participants? How will freedom from STIs and UTIs be determined? Why is having two or more of the same STI an exclusion criteria (versus any or 3 or more)? Will pregnancy testing be performed?

What medical history will be conducted, and who will perform it?

Who will be available in the event of an SAE?

Who will obtain informed consent?

How will mutual monogamy be determined (for example, on separate questionnaires for couples which are then matched?)

Why are persons over the age of 45 not eligible?

Given the risk for HIV and STDs among men who have sex with men (MSM), have the investigators considered enrolling this group into the study, or are the condoms being tested exclusively for penile-vaginal intercourse? If so, this should be specified.

Finally, the investigators should seriously consider performing genital exams to determine baseline status, or provide some justification for not doing so. This seems especially important with regard to assessing pre-existing or new STIs.

Innovation: The proposal to develop a silicone-based condom is innovative.

Investigators: While having no experience in prior clinical studies, the investigator has assembled a well experienced research team. However, more information should be provided re: how the investigator plans to coordinate this team.

Environment: The environments described are adequate for the work being proposed.

Protection of Human Subjects from Research Risks: No specific information is provided with regard to a DSMB. More information is required on who will be assessing and recording adverse events.
Inclusion of Women Plan: Satisfactory
Inclusion of Minorities Plan: Satisfactory
Inclusion of Children Plan: Satisfactory

Overall Evaluation: An innovative, significant, ambitious proposal. Enthusiasm is somewhat dampened by timeline and lack of details regarding study coordination and procedures.

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:
PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE
INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE
INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE
INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE
VERTEBRATE ANIMAL (Resume): ACCEPTABLE
COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

MEETING ROSTER
Center for Scientific Review Special Emphasis Panel
CENTER FOR SCIENTIFIC REVIEW
ZRG1 AARR-G (15) B
July 13, 2005

CHAIRPERSON
LORD, SARAH E, PHD
DIRECTOR, COLLEGE HEALTH PROGRAMS
INFLEXXION
NEWTON, MA 02459

MEMBERS
BOOTH, ROBERT E, PHD
PROFESSOR
DEPARTMENT OF PSYCHIATRY
SCHOOL OF MEDICINE
UNIVERSITY OF COLORADO HEALTH SCIENCES CENTER
DENVER, CO 80206

COLFAX, GRANT N, MD
DIRECTOR OF HIV PREVENTION STUDIES
SAN FRANCISCO DEPT OF PUB HEALTH
AIDS OFFICE-HIV RESEARCH SECTION
SAN FRANCISCO, CA 94102

COON, DAVID W, PHD
RESEARCH SCIENTIST
DEPT. OF SOC. & BEH. SCIENCES
ARIZONA STATE UNIVERSITY
GLENDALE, AZ 853064908

DI NOIA, JENNIFER , PHD
ASSOCIATE RESEARCH SCHOLAR
SCHOOL OF SOCIAL WORK
COLUMBIA UNIVERSITY
NEW YORK, NY 10025

JOHNSON, MALLORY O, PHD
RESEARCH SPECIALIST
CENTER FOR PREVENTION STUDIES
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
SAN FRANCISCO, CA 94105

JONES, RACHEL , PHD
ASST. PROFESSOR
DEPARTMENT OF NURSING
RUTGERS, STATE UNIV. OF NEW JERSEY
NEWARK, NJ 07102

KALICHMAN, SETH C, PHD
PROFESSOR

DEPARTMENT OF PSYCHOLOGY
UNIVERSITY OF CONNECTICUT
STORRS, CT 06269-1020

METSCH, LISA R, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF EPIDEMIOLOGY AND PUBLIC HEALTH
SCHOOL OF MEDICINE
UNIVERSITY OF MIAMI
MIAMI, FL 33136

MORGAN, ROBERT O, PHD
ASSOCIATE PROFESSOR
HOUSTON CENTER FOR QUALITY OF CARE AND
UTILIZATION STUDIES
VA MEDICAL CENTER
HOUSTON, TX 77030

MOROKOFF, PATRICIA J, PHD
PROFESSOR & DIRECTOR OF CLINICAL PSYCHOLOGY
DEPARTMENT OF PSYCHOLOGY
CANCER PREVENTION RESEARCH CENTER
UNIVERSITY OF RHODE ISLAND
KINGSTON, RI 02881

OBERMAYER, JAMI L, PHD
RESEARCH SCIENTIST
PICS, INC
RESTON, VA 20191

PARSONS, JEFFREY T, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF PSYCHOLOGY
HUNTER COLLEGE
CITY UNIVERSITY OF NEW YORK
NEW YORK, NY 10021

SAFREN, STEVEN A, PHD
ASSISTANT PROFESSOR, HARVARD MEDICAL SCHOOL
DEPARTMENT OF PSYCHIATRY
MASSACHUSETTS GENERAL HOSPITAL
BOSTON, MA 02115

STRAUSS, RONALD P, DMD, PHD
PROFESSOR AND CHAIR
DEPARTMENT OF DENTAL ECOLOGY
SCHOOL OF DENTISTRY
UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
CHAPEL HILL, NC 27599-7450

STROMBECK, RITA D., PHD
PRESIDENT
HEALTHCARE EDUCATION ASSOCIATES
PALM SPRINGS, CA 92264

WELLS, JENNIFER JANE, PHD
CEO
TECHNOLOGICAL ASSISTANCE INSTITUTE
FOR INTELLECTUAL DISABILITY
DEXTER, OR 97431

YBARRA, MICHELE , MPH, PHD

PRESIDENT
INTERNET SOLUTIONS FOR KIDS INC
IRVINE, CA 92618

MAIL REVIEWER(S)
CARTER, ELI , BS
DIRECTOR
FAMILY HEALTH INTERNATIONAL
RESEARCH TRIANGLE PARK, NC 27709

SCIENTIFIC REVIEW ADMINISTRATOR
RUBERT, MARK P., PHD
SCIENTIFIC REVIEW ADMINISTRATOR
CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892

GRANTS TECHNICAL ASSISTANT
GIRI, DIMPLE C.
GRANTS TECHNICAL ASSISTANT
CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892
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